

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Group Art Unit 1617

Patent Application of

Richard B. Mazess

Application No. 09/995,911

Confirmation No.: 4126

Filed: November 28, 2001

Examiner: Criares, Theodore

I, Sally J. Sorensen, hereby certify that this correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of my signature.

Sally Sorensen
Signature

March 2, 2004
Date of Signature

TREATMENT OF HYPERPROLIFERATIVE
DISEASES USING ACTIVE VITAMIN D
ANALOGUES

FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 CFR §1.97(c)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Examiner's attention is directed to the references which are listed on the attached Form PTO/SB/08B. Copies of the references are attached. This Statement is also being accompanied by a check in payment of the \$180.00 fee required under 37 CFR §1.17(p). Please charge or credit Deposit Account No. 50-0842 with any shortage or overpayment of the required fee. Citation of these references is respectfully requested.

No concession is made that these documents are prior art, and Applicant expressly reserves the right to antedate the documents as may be appropriate.

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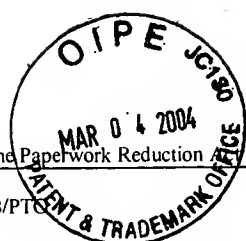
Respectfully submitted,

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Substitute for form I449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	09/995,911
				Filing Date	November 28, 2001
				First Named Inventor	Mazess et al.
				Group Art Unit	1617
				Examiner Name	Theodore J. Criares
Sheet	1	of	2	Attorney Docket Number	017620-9335

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.

	DE	Albert, D.M. et al., "Verhoeff's Query: Is Vitamin D Effective Against Retinoblastoma?," <i>Arch. Ophthalmol</i> (1988) 106:536-540.
	DF	Cohen, S.M. et al., "Further Studies of the Effect of Vitamin D on Retinoblastoma," <i>Arch. Ophthalmol</i> (1988) 106:541-543.
	DG	Colston, K.W. et al., "Possible Role for Vitamin D in Controlling Breast Cancer Cell Proliferation," <i>Lancet</i> (Jan. 28, 1989) 188-191.
	DH	Colston, K. et al., "1,25-Dihydroxyvitamin D ₃ and Malignant Melanoma: The Presence of Receptors and Inhibition of Cell Growth in Culture," <i>Endocrinology</i> (1981) 108:3:1083-1086.
	DI	Colston, K.W. et al., "Effects of Synthetic Vitamin D Analogues on Breast Cancer Cell Proliferation <i>In Vivo</i> and <i>In Vitro</i> ," <i>Biochemical Pharmacology</i> (1992) 44:4:693-702.
	DJ	Cross, H.S. et al., "Antiproliferative Effect of 1,25-Dihydroxyvitamin D ₃ and its Analogs on Human Colon Adenocarcinoma Cells (CACO-2): Influence of Extracellular Calcium," <i>Biochem. Biophysical Res. Comm.</i> (1991) 179:1:57-62.
	DK	Cross, H.S. et al., "Growth Inhibition of Human Colon Adenocarcinoma-Derived Caco-2 Cells by 1,25-Dihydroxyvitamin D ₃ and Two Synthetic Analogs: Relation to In Vitro Hypercalcemic Potential," <i>Archives of Pharmacology</i> , (1993) 347:105-110.
	DL	Etsuko, A. et al. "Differentiation of Mouse Myeloid Leukemia Cells Induced by 1 α ,25-Dihydroxyvitamin D ₃ ," <i>Proc. Natl. Acad. Sci.</i> (1981) 78:8:4990-4994.
	DM	Hedlund, T.E. et al., "Vitamin D Receptor Expression is Required for Growth Modulation by 1 α ,25-Dihydroxyvitamin D ₃ in the Human Prostatic Carcinoma Cell Line ALVA-31," <i>J. Steroid Biochem. Molec. Biol.</i> (1996) 58:3:277-288.
	DN	Hedlund, T.E. et al., "Stable Expression of the Nuclear Vitamin D Receptor in the Human Prostatic Carcinoma Cell Line JCA-1: Evidence that the Antiproliferative Effects of 1 α ,25-Dihydroxyvitamin D ₃ are Mediated Exclusively Through the Genomic Signaling Pathway," <i>Endocrinology</i> (1996) 137:5:1554-1561.
	DO	Higashimoto, Y. et al., "1 α ,25-Dihydroxyvitamin D ₃ and All-Trans-Retinoic Acid Inhibit the Growth of a Lung Cancer Cell Line," <i>Anticancer Research</i> (1996) 16:2653-2660.
	DP	Honma, Y. et al., "1 α ,25-Dihydroxyvitamin D ₃ and 1 α -Hydroxyvitamin D ₃ Prolong Survival Time of Mice Inoculated with Myeloid Leukemia Cells," <i>Cell Biology</i> (1983) 80:201-204.
	DQ	McElwain, M.C. et al., "Antiproliferative Effects <i>In Vitro</i> and <i>In Vivo</i> of 1,25-Dihydroxyvitamin D ₃ and a Vitamin D ₃ Analog in a Squamous Cell Carcinoma Model System," <i>Molecular and Cellular Differentiation</i> , (1995) 3(1):31-50.
Examiner Signature		Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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				Application Number	09/995,911
				Filing Date	November 28, 2001
				First Named Inventor	Mazess et al.
				Group Art Unit	1617
				Examiner Name	Theodore J. Criares
Sheet	2	of	2	Attorney Docket Number	017620-9335

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
DR	Mehta, R.G. et al., "Prevention of Preneoplastic Mammary Lesion Development by a Novel Vitamin D Analogue, 1 α -Hydroxyvitamin D ₃ ," <i>J. National Cancer Inst.</i> (1997) 89:3:212-218.	
DS	Peehl, D.M., et al., "Antiproliferative Effects of 1,25-Dihydroxyvitamin D ₃ on Primary Cultures of Human Prostatic Cells," <i>Cancer Research</i> (1994) 54:805-810.	
DT	Schwartz, G.G. et al., "Human Prostate Cancer Cells: Inhibition of Proliferation by Vitamin D Analogs," <i>Anticancer Research</i> (1994) 14:1077-1082.	
DU	Schwartz, G.G. et al., "1,25-Dihydroxy-16-Ene-23-Yne-Vitamin D ₃ and Prostate Cancer Cell Proliferation <i>In Vivo</i> ," <i>Urology</i> (1995) 46:3:365-369.	
DV	Shabahang, M. et al., "The Effect of 1,25-Dihydroxyvitamin D ₃ on the Growth of Soft-Tissue Sarcoma Cells as Mediated by the Vitamin D Receptor," <i>Annals of Surgical Oncology</i> (1996) 3:2:144-149.	
DW	Skowronski, R.J. et al., "Actions of Vitamin D ₃ Analogs on Human Prostate Cancer Cell Lines: Comparison with 1,25-Dihydroxyvitamin D ₃ ," <i>Endocrinology</i> (1995) 136:1:20-26.	
DX	Skowronski, R.J. et al., "Vitamin D and Prostate Cancer: 1,25 Dihydroxyvitamin D ₃ Receptors and Actions in Human Prostate Cancer Cell Lines," <i>Endocrinology</i> (1993) 132:5:1952-1960.	
DY	Tokuumi, Y. "Correlation Between the Concentration of 1,25 α Dihydroxyvitamin D ₃ Receptors and Growth Inhibition, and Differentiation of Human Osteosarcoma Cells Induced by Vitamin D ₃ ," <i>J. Jpn. Orthop. Assoc.</i> (1995) 69:181-190.	
DZ	Yabushita, H. et al., "Vitamin D Receptor in Endometrial Carcinoma and the Differentiation-Inducing Effect of 1,25-Dihydroxyvitamin D ₃ on Endometrial Carcinoma Cell Lines," <i>J. Obstet. Gynaecol. Res.</i> (1996) 22:6:529-539.	
EA	Zhou, J. et al., "Novel Vitamin D Analogs that Modulate Leukemic Cell Growth and Differentiation with Little Effect on Either Intestinal Calcium Absorption or Bone Calcium Mobilization," <i>Blood</i> (1989) 74:1:82-93.	
EB	Zhuang, S-H, et al., "Vitamin D Receptor Content and Transcriptional Activity do not Fully Predict Antiproliferative Effects of Vitamin D in Human Prostate Cancer Cell Lines," <i>Molecular and Cellular Endocrinology</i> (1997) 126:83-90.	
EC	Zugmaier, G., et al., "Growth-Inhibitory Effects of Vitamin D Analogues and Retinoids on Human Pancreatic Cancer Cells," <i>British Journal of Cancer</i> (1996) 73:1341-1346.	
ED	<i>Proceedings of the American Association for Cancer Research</i> (1997) 38:456.	

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